ISRCTN15214459 https://doi.org/10.1186/ISRCTN15214459

Effectiveness and cost-effectiveness study of the Liaison Mental Health-Education Program for schools

Submission date
29/05/2024

Recruitment status
Recruiting

Registration date
23/06/2024

Overall study status
Ongoing

Last Edited
07/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schools play a crucial role in the development of children and adolescents. Mental health prevention and intervention programs in schools can serve as tools for early detection and management of mental health issues among students. This study aims to evaluate the effectiveness and cost-effectiveness of a mental health prevention, promotion, and intervention program implemented in various schools in the Community of Madrid (Comunidad de Madrid), Spain. It involves a community child and adolescent mental health resource for coordination and liaison between educational centers and child and adolescent mental health services in the healthcare area of Hospital G.U. Gregorio Marañón and Hospital U. del Sureste, in Comunidad de Madrid. Each clinical team includes a psychiatrist, a child and adolescent clinical psychologist, and a mental health specialized nurse.

Who can participate?
All students from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain) where the mental health coordination and liaison program has been implemented will be invited to participate, as well as students from control schools. Additionally, parents of these students and teachers from participating schools will be offered participation. For the research study on the effectiveness of clinical sub-programs, all children and adolescents included in these sub-programs, who agree to participate and provide informed consent, will be included.

What does the study involve?
All students from participating schools will be informed about the study. Individuals who agree to participate and provide informed consent will be assessed at the start of the study and after 6, 12, and 24 months. For the effectiveness study of clinical sub-programs, participation will be offered to all students included in these sub-programs. Recruitment, assessment, data collection, and follow-up will be conducted by healthcare professionals from the liaison program. Throughout the 12-month follow-up period for each case in the clinical sub-programs effectiveness study, information related to program accessibility, effectiveness indicators, and efficiency will be collected. The evaluation will involve the application of clinical scales (self and

hetero-administered) and the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

What are the possible benefits and risks of participating?
There are no risks associated with participating in this study. Participation will not result in direct benefits. Participants will be contributing to a better understanding of the effects of a mental health prevention and promotion program for children and adolescents.

Where is the study run from?
Hospital General Universitario Gregorio Marañón (Spain)

When is the study starting and how long is it expected to run for?
October 2023 to November 2026

Who is funding the study?
1. Fundación Alicia Koplowitz (Spain)
2. Fundación Nemesio Díez (Spain)

Who is the main contact?
Dr Celso Arango López, carango@hggm.es

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Celso Arango

ORCID ID
https://orcid.org/0000-0003-3382-4754

Contact details
Instituto de Psiquiatría y Salud Mental
Calle Ibiza, 43
Madrid
Spain
28009
+34 (0)915868133
carango@hggm.es

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number

PSY-SCHOOL 1.0

Study information

Scientific Title
Effectiveness and cost-effectiveness study of the Coordination and Liaison Child and Adolescent Mental Health Program for schools

Acronym
PSY-SCHOOL

Study objectives
The mental health coordination and liaison program for schools will constitute an effective and cost-effective intervention. Patients included in the clinical subprograms will present, 12 months after the inclusion in the program, or upon being discharged from it, an improvement in their overall functionality, in their quality of life and a lesser severity on their psychopathology.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/01/2024, Ethics committee of research with medicines Hospital General Universitario Gregorio Marañón (C/ Dr. Esquerdo 46, Pabellón de Gobierno, Primera Planta, Madrid, 28007, Spain; +34 (0)91 586 7007/91 or +34 (0)91 426 9378; ceim.hgugm@salud.madrid.org), ref: PSY-SCHOOL

Study design
Observational prospective longitudinal study

Primary study design
Observational

Study type(s)
Other, Efficacy

Health condition(s) or problem(s) studied
Child and adolescent mental health disorders

Interventions
All students from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain), where the mental health coordination and liaison program has been implemented, will be invited to participate, as well as students from control schools. Additionally, parents of these students and teachers from participating schools will be offered participation. Individuals who agree to participate and provide informed consent will be assessed at baseline and 6, 12, and 24 months from the start of the study. The evaluation will involve the application of questionnaires and scales (self and hetero-administered) and the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

For the effectiveness study of the clinical sub-programs (the clinical assessment subprogram and the coordination subprograms that provide case-management/coordination for the students with a diagnosed mental health condition, attending a public mental health resource), all children and adolescents included in these sub-programs, who agree to participate and provide informed consent will be included. For this part of the study, recruitment, assessment, data collection, and follow-up will be conducted by healthcare professionals from the liaison program; throughout a 12-month follow-up period. For each case in the clinical sub-programs effectiveness study, information related to program accessibility, effectiveness indicators, and efficiency will also be collected. The evaluation will involve the application of clinical scales (self and hetero-administered) and also the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

Intervention Type
Other

Primary outcome(s)
1. Cost-effectiveness of the program will be evaluated by measuring:
1.1. Behavioural and emotional difficulties of the participants measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 6, 12 and 24 months of follow-up
1.2. Health-related quality of life of children and adolescents measured using the EQ-5D-Y at baseline, 6, 12 and 24 months of follow-up
1.3. Mental well-being measured in parents and teachers using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 6, 12 and 24 months of follow-up
1.4. Impact of the program on the educational system measured by extracting information from school records (e.g., academic performance, school absenteeism, number of cases of bullying) at baseline, 6, 12 and 24 months of follow-up
1.5. Direct and indirect healthcare and social costs of the program, measured using short questionnaires ad hoc, as well as extracting information from school records, at baseline, 6, 12 and 24 months of follow-up
1.6. Direct implementation costs of the program (e.g., clinicians salaries)

2. Effectiveness of the clinical sub-programs is evaluated with the following variables and measures:
2.1. Overall functionality (in children and adolescents) measured using the Children's Global Assessment Scale (CGAS) at baseline, 6 and 12 months of follow-up.
2.2. Severity of the psychopathology (in children and adolescents) measured using the Clinical Global Impressions-Severity (CGI-S) at baseline, 6 and 12 months of follow-up.
2.3. Improvement of the psychopathology (in children and adolescents) measured using the CGI-I at 6 and 12 months of follow-up.
2.4. Specific psychopathological symptoms (in children and adolescents) measured using specific clinical scales (such as the Hamilton Depression Rating Scale [HDRS], Positive and Negative Syndrome Scale [PANSS]), according to clinician criteria, at baseline, 6 and 12 months of follow-up.
2.5. Health-related quality of life of children and adolescents measured using the EQ-5D-Y at baseline, 6 and 12 months.

Key secondary outcome(s))
1. Satisfaction with the Mental Health Clinical Liaison Program, measured in teachers and clinicians (from other mental health services where participants are attended), using a self-device questionnaire, based on the general satisfaction questionnaire administered in other

programs/services at the Gregorio Marañón Hospital at 12 months of follow-up or after the patient has been discharged.
2. Accessibility measured using the following indicators at baseline:
2.1. Response time (measured in hours/days): the time difference between the patient referral date and the date the patient is included in the subprogram
2.2. Origin of referral
2.3. Acceptance of referral
3. Efficiency measured using the following indicators after 12 months of follow-up (or after the patient has been discharged):
3.1. Number of discharges
3.2. Average length of stay in the subprogram
3.3. Number of visits per clinician
3.4. Referrals to other public mental health services (such as the community mental health centre)

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. All students (age 3 to 19 years) from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain) where the mental health coordination and liaison program has been implemented, as well as students from the control schools selected. Parents of these students and teachers from participating schools, as well as from control schools.
2. For the part of the study on the effectiveness of the clinical sub-programs, all students (aged 3 to 19 years) from schools (public and private) where the mental health coordination and liaison program has been implemented, and that are included in these sub-programs. Parents of these students.
3. Informed consent provided by students, parents and teachers.

Participant type(s)
Patient, Learner/student, Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
19 years

Sex
All

Key exclusion criteria
None

Date of first enrolment
15/05/2024

Date of final enrolment
30/07/2026

Locations

Countries of recruitment
Spain

Study participating centre
Instituto de Psiquiatría y Salud Mental, Hospital General Universitario Gregorio Marañón
Calle Ibiza, 43.
Madrid
Spain
28009

Sponsor information

Organisation
Instituto de Psiquiatria y Salud Mental, Hospital Gregorio Marañón

Funder(s)

Funder type
Charity

Funder Name
Fundación Alicia Koplowitz

Alternative Name(s)
Alicia Koplowitz Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Spain

Funder Name
Fundación Nemesio Díaz

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Dr Celso Arango (carango@hggm.es).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1		06/06/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes